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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,978	01/22/2004	David Hung	12.024011	5996
38732	7590	03/06/2006	EXAMINER	
CYTYC CORPORATION 250 CAMPUS DRIVE MARLBOROUGH, MA 01752			MARMOR II, CHARLES ALAN	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 03/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/762,978	<b>Applicant(s)</b> HUNG ET AL.	
	<b>Examiner</b> Charles A. Marmor, II	<b>Art Unit</b> 3736	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 79-89 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 79-89 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

## **DETAILED ACTION**

### ***Oath/Declaration***

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

### ***Specification***

2. The disclosure is objected to because of the following informalities:
  - a. In the replacement paragraph spanning lines 5-12 of page 1, at line 2, -- now U.S. Patent No. 6,689,070,-- should be inserted following “2002,”.
  - b. In the replacement paragraph spanning lines 5-12 of page 1, at line 5, “1999 and each” should read --1999, now U.S. Patent No. 6,413,228, which claims the benefit of each--.Appropriate correction is required.

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### ***Claim Objections***

4. Claims 79 and 83 are objected to because of the following informalities:

a. At claim 79, line 2, --breast-- should be inserted before “duct”.

b. At claim 83, line 3, “the distal” should read --a distal--.

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 79-85 and 89 are rejected under 35 U.S.C. 102(e) as being anticipated by Love ('622). Love teaches a ductal access device for accessing a breast duct and collecting cellular material from within the duct. The device includes an elongated accessing member (50) having a proximal end, a distal end, and an internal lumen (54,56) extending between the ends (note the use of the transitional phrase “comprising” which is inclusive or open-ended and does not exclude additional, unrecited elements, see MPEP 2111.02). The distal end includes a port (58, 60). The proximal end includes an opening (64,66) for infusion or withdrawal of lavage fluid. An elongate guide member (guidewire, see at least column 6, lines 49-54) extends through the internal lumen for positioning the accessing member in a breast duct. The port is connected to a syringe (84) which may be considered a fluid collection device.

Regarding claims 83-85 and 89, note that the claims do not require that the infusion and withdrawal of lavage fluid occur through the same, single lumen. The distal end of the catheter is inserted through a ductal orifice and into the distal lumen of a duct or ductal network; lavage fluid is infused into the duct or ductal network through a lumen of the catheter; and the lavage fluid and substances borne thereby are withdrawn from the duct or ductal network through a lumen of the catheter. A positive infusion pressure is applied through the catheter by a syringe. The breast is externally massaged (positive external pressure) so that fluid is forced in the direction of the catheter.

7. Claims 79-89 are rejected under 35 U.S.C. 102(b) as being anticipated by Hou et al. (Radiology 1995). Hou et al. teach a method for obtaining material from a human breast duct via ductal lavage. The method includes the steps of inserting a single lumen ductal access catheter device into a breast duct; inserting the distal portion of the catheter device through the ductal orifice and into a duct lumen; introducing a wash fluid through the single lumen of the catheter device into the duct; and withdrawing/collecting the wash fluid and any substances carried thereby from the duct through the single lumen of the catheter device while the device is in the duct. The wash fluid is introduced to a single breast milk duct and collected from the same milk duct without mixing with materials from other breast milk ducts. Manual pressure (massaging and squeezing) is applied to the breast tissue after introducing the wash fluid. The wash fluid is introduced to a volume of 2 ml prior to collecting any of wash fluid from the duct. The wash fluid is present in the duct for a preselected time in the range from one second to one hour (i.e., 5-10 minutes). The retrieved fluid is collected in a collection syringe that is connected to a hub

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of the device and generates a negative pressure within the hub to draw the retrieved fluid into the collection syringe. The guiding suture extends through the elongated accessing catheter to form an elongated guide member.

### ***Double Patenting***

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 79-89 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7-11, 21, 22, 50, 52 and 62-77 of U.S. Patent No. 6,689,070. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claims of the patent and the claims of the instant application recite ductal access devices and methods for obtaining material from (lavaging) human breast ducts including the same basic structural elements and method steps. Since the claims of the

instant application are “anticipated” by the claims of the patent, the claims are not patentably distinct.

10. Claims 79-81 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-7, 20, 31, 35, 48, 49, 69, 76, 79-81, 87 and 90 of U.S. Patent No. 6,413,228. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent disclose ductal access devices including substantially the same structural functional limitations that are merely claimed using different terminology. Since the claims of the patent “anticipate” the claims of the instant application, the claims are not patentably distinct.

11. Claim 83 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 16 of U.S. Patent No. 6,673,024. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claims of the patent and the claim of the instant application recite methods for obtaining material from (lavaging) human breast duct including the basic steps of introducing an access device into a duct, introducing a wash fluid through the lumen, and collecting at least a portion of the wash fluid through the lumen. The patent is more narrow, reciting the apparatus used to perform the method as a ductal access tool having an internal lumen, rather than the more general catheter recited by the claim of the instant application. The patent claims include additional limitations not required by the claim of the instant application. Since the “broader” claim of the instant application is “anticipated” by the claims of the patent, the claims are not patentably distinct.

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12. Claim 83 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5 and 13 of U.S. Patent No. 6,642,009. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claims of the patent and the claim of the instant application recite methods having generally the same core method steps. The patent claims are directed to methods for aiding in the diagnosis of breast cancer which include all of the method steps for lavaging a breast duct of the application claim, plus additional steps not required by the application claim. The patent is more narrow at least in reciting the apparatus used to perform the method as a ductal access tool having an internal lumen, rather than the more general catheter recited by the claim of the instant application. Since the “broader” claim of the instant application is “anticipated” by the claims of the patent, the claims are not patentably distinct.

13. Claim 83 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19 and 23 of U.S. Patent No. 6,638,727. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claims of the patent and the claim of the instant application recite methods for obtaining material from human breast duct including a method for lavaging the duct including the same basic method steps. The patent claims include additional limitations not required by the claim of the instant application. Since the “broader” claim of the instant application is “anticipated” by the claims of the patent, the claims are not patentably distinct.



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14. Claim 83 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,610,484. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claims of the patent and the claim of the instant application recite methods for obtaining material from (lavaging) a human breast duct including the basic steps of introducing a single lumen access device into a duct, introducing a wash fluid through the lumen, and collecting at least a portion of the wash fluid through the lumen, while the patent claims include additional limitations not required by the claims of the instant application. Since the “broader” claim of the instant application is “anticipated” by the claims of the patent, the claims are not patentably distinct.

15. Claim 83 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5 and 8 of U.S. Patent No. 6,494,859. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claims of the patent and the claim of the instant application recite methods for obtaining material from (lavaging) a human breast duct including the basic steps of introducing a single lumen access device into a duct, introducing a wash fluid through the lumen, and collecting at least a portion of the wash fluid through the lumen, while the patent claims include additional limitations not required by the claims of the instant application. Since the “broader” claim of the instant application is “anticipated” by the claims of the patent, the claims are not patentably distinct.

*Conclusion*

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II  
Primary Examiner  
Art Unit 3736

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March 1, 2006